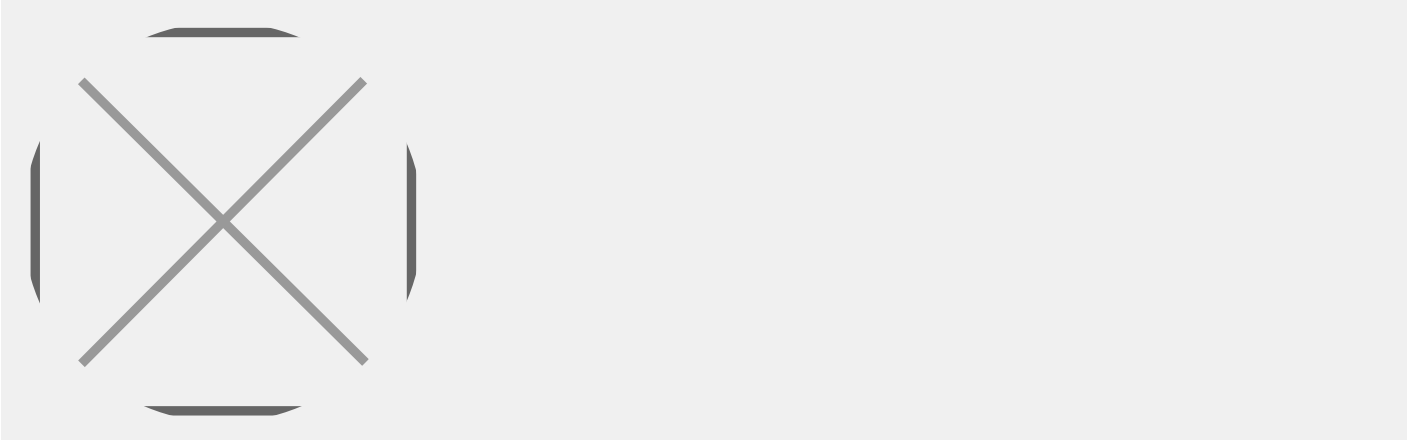
Interview with Daara Patel, Indian Drug Manufacturers' Association (IDMA)



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Since we last met in 2006, the Indian pharmaceutical industry has been doing very well indeed, as a very large number of drugs came off patent. This trend will continue in the coming years. Today this is a crucial moment for India: the industry is at a crossroad. How has the Indian pharmaceutical sector changed in these last years, and are you ready to seize tomorrow's opportunities?

Traditionally, India's strength has been in generics. If you compare India with other countries, as far as patented products and branded products are concerned, we are still behind because a lot of money, a lot of tenacity, and a lot of time are required for new molecule discovery. Very few companies are on that track right now—hardly three, maximum four, big Indian companies. I do not see much happening in that area in the future unless the government steps up support for R&D—through investment or providing incentives such as tax benefits—and unless Indian companies have greater interaction with academia, as is happening in the West, and even in China now. We are still lagging behind, and unless we do that it will be difficult for us to innovate.

But having said that, our strength has been in generics and now even big players are getting into generics. Our industry is starting to understand that if you want to grow, you need to shift from vanilla generics to value-added generics and that is happening. So the scope is there. It is not that the companies do not have the muscle or the infrastructure to manufacture world-class products, because that is already in place. Outside of the U.S., India has the largest amount of companies filing DMFs and ANDAs, the largest amount of U.S. FDA-approved plants: 169! Not to mention

more than 1000 plants approved by WHO.

The momentum is good for Indian companies, with all the in-licensing agreements taking place. The international companies have confidence in India and Indian companies, so they give the entire know-how, the raw materials, all the ingredients, all the sourcing to India and the goods are produced here only for export. There are so many 100% export-oriented units in India. So yes, we are doing well: if you look at numbers, the entire sector has grown to become a $20Bn-plus industry—of which almost 40-45% is exports. And thanks to our infrastructure, we have the capacity to grow more.

An association like yours represents more than 750 companies throughout the industry, from the largest Indian flagship companies to some very small manufacturers. Naturally, they have different interests and face different challenges. How do you manage to represent all of your members?

This is the beauty of IDMA! The industry is walking and we carry everybody with us. Do not forget that the IDMA was formed to protect the interests of the national-sector companies. But now we know that we need to step up the way we function, look at new products, and we need to step up quality—we can read the writing on the wall. While different companies are pursuing different goals, our basic aim is very clear: we want all of our members to know what is going on globally, we want to train our members and they have to come up to standard. Several of our members know their shortcomings, so there are mergers and acquisitions, and certain small players—regional or local players mainly—have to wind up or tie up with other players and capitalize on their strengths. If their strength is marketing, then they have to find a partner for production, and vice versa.

There is still an image issue associated with the “made in India” brand—especially in Europe and the US—involving quality concerns, fear of counterfeit drugs, and a general mistrust. How do you face this challenge, what do you do as an association to promote “made in India?”

We have a lot of training programs. We tell our members how to upgrade to cGMP, and to comply with WHO and U.S. FDA standards. IDMA has a lot of seminars where people from the FDA come and talk to our members about new technologies, new products, how to harmonize their practices and adapt to the different standards. Our concentration is on quality. We also have to protect them from being counterfeited with anti spurious seminars on how to protect our products—with bar coding, holograms, etc.

Recently, we have also supported CDSCO to carry out a survey on spurious drugs. Within 15000 samples, we found only 0.02% contained spurious drugs. This is negligible, especially as the Indian market is so huge—in volume and in value! There are 50000 formulations floating in the country,

12000 manufacturers and the market is almost $10Bn! So from that, 0.02% spurious drugs is nothing. But the U.S. and Europe are trying to malign the image of Indian companies, which is why they are raising the issue of spurious drugs being made in India.

It is not right. For example, they have also held our containers when those goods were only in transit, and not meant for consumption in that country! They know that Indian companies have the know-how and the tenacity to make quality products, and we are cost-competitive on top of it, so they are trying various means to protect their industry—bringing in spurious drugs issues, data exclusivity issues, etc.—to which we say no!

Is the debate about IP protection another way of putting up entry barriers for Indian generic companies?

Exactly. Just barriers. As far as TRIPS is concerned, we totally agree and support the text. At the IDMA, we are clear about two things: first, the innovator has to be rewarded properly—we respect patents. Secondly, the Indian consumer's interest has to be superior. It is very clear.

The relationship between MNCs and Indian companies seems to be one of love and hate. There are so many collaborations: there is a boom in licensing agreements, sourcing tie ups, and etc. But at the same time, there is a little concern in the domestic industry as MNCs grow their market share and acquire local companies. Where is the balance?

They are buying off our industry! So the government has put up solid rules about FDI. Foreign Direct Investment cannot be more than 49%. We need them of course, which is why they can acquire up to 49%. Like this, as far as training of staff and quality are concerned, as far as getting new products, getting new technologies—nobody can complain. But we do not want them to dominate the market and raise consumer prices afterwards. This can happen if they have a total takeover.

How do you view competition from China?

China has inherent quality and credibility problems. Now, of course, they are getting over it as far as bulk drugs are concerned. They have huge-capacity plants, they make only one or two raw materials per plant, they have government support that we do not have, and they do not compete amongst themselves—they all work together with the government's direct support. Their line cost is very light, the cost of interest is very low, and they do not have labor problems like we have. Again, they have lots of support from the government—and this is why they manage to be so competitive. And given their capacity, they can manage such low prices that we have no choice but to buy from them.

However, in formulations, we still have an edge over them; we actually are far better than them. And it will not be that easy for China to catch up. Furthermore, China is getting oriented towards

the European pharmacopeia, whereas traditionally, India is more aligned with U.S. FDA procedures and standards. We can already see that now, and it is going to take them a couple of years to match our formulations skills.

But when it happens, what are you going to do?

When it happens, we will join China, and become Chindia! We are actually already trying to work together, which is why people call us Chindia. We believe that, in global tenders, if China and India do not compete, and take advantage of the synergy benefits that they enjoy (for example, we buy API from them, and they give us formulations to manufacture), we can do wonders and we can take on the U.S. and European countries.

India has been growing at a pace of 22% year-on-year for many years now. Are these growth figures sustainable?

This type of double-digit growth cannot continue for long obviously. It is as simple as that. It all depends now on how the markets react; how countries look at India. Today, out of our total production, 50% is geared towards exports. And many big companies are outsourcing to India, because they have trust in the Indian industry. So if that trend continues, we will continue to have double-digit growth. But in any case, we will continue to do better than global pharmaceutical growth, at least for the next ten years.

So if we come back in five years time, where do you think the industry will be standing?

There will be few players, or at least not as many as today. You will see that some Indian companies will have come up with their own innovative products and molecules. We will probably be doing very well as far as value-added generics are concerned. You will see that more multinationals, and more big Indian companies, the so-called Indian multinationals, have ties with medium-sized, good-quality Indian companies. The market for clinical research will have opened up—people will come here to do their clinical trials and R&D. And finally, the dependence on Indian generics will certainly increase.

That is a lot of change in five years!

Well, if all does not happen in the next five years, I have no doubt that it will by 2020.

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